

Remarks

Claims 1-8, 17-23 and 28 are pending. The subject matter from claim 13 has been incorporated into claims 1 and 17. Claims 2 and 3 have been amended to make proper reference to corresponding elements from which they depend. No new matter has been added.

The Examiner rejects claims 2 and 3 under 35 U.S.C. 112 for reciting elements lacking proper antecedent basis. Claims 2 and 3 have been amended to correct this deficiency. The Examiner rejects claims 8 and 23 under 35 U.S.C. 112 as being indefinite for failing to particularly point out and distinctly claim the intended subject matter. The Examiner objects, in particular, to the use of “substantially” free of pores. This feature is described in the Specification on page 20, last paragraph. Additionally, a test method is provided on the following two pages. Applicants submit that the Specification provides sufficient background information for one skilled in the art to understand the metes and bounds of a dosage form that is substantially free of pores.

The Examiner rejects claims 1, 2, 6-8, 17, 18, 22 and 23 under 35 U.S.C. 103 as being unpatentable over published PCT application WO 99/20745 (“WO ‘745”) in view of U.S. Patent No. 5,922,352 (“Chen et al.”). The Examiner rejects claims 4, 5, 20 and 21 under 35 U.S.C. 103 as being unpatentable over WO ‘745 in view of Chen and further in view of U.S. Patent No. 5,756,123 (“Yamamoto et al.”). Applicants respectfully traverse this rejection.

Claim 1 is now directed to dosage form comprising a compressed core and an overcoated shell portion that comprises a composition comprising 40 to 95 weight percent of a water soluble polymer having a cloud point from about 20 to about 90° C, 5 to 25 weight percent carrageenan, and 0.5 to 5 weight percent gellan gum. Claim 17 is now directed to a dosage form comprising a compressed core and an overcoated shell portion that comprises a composition comprising 40 to 95 weight percent of a water soluble polymer having a cloud point from about 20 to about 90° C, 5 to 40 weight percent of one or more carrageenans, and 0.5 to 30 weight percent lubricant. These claims have been amended above to provide that the dosage form contains a pharmaceutical active ingredient that is released from the dosage

form in a burst release fashion. This subject matter was originally recited in claim 13, thereby rendering both of these obviousness rejections moot.

The Examiner rejects claims 3, 13, 19 and 28 under 35 U.S.C. 103 as being unpatentable over WO '745 in view of Chen and in further view of U.S. Patent No. 4,992,277 ("Sangekar et al."). The Examiner asserts that Sangekar discloses a coating that produces a dosage form having an immediate release profile. The Examiner alleges that the claimed phrase "burst release" is not defined in the Specification and therefore the claimed dosage form is encompassed by tablet having an immediate release coating. Applicants respectfully traverse this rejection.

Burst release is actually defined in the Specification as "release of the active ingredient from the dosage form [that] is delayed for a pre-determined time after ingestion by the patient, after which it is promptly released". See page 23. Additionally, burst release profiles are exemplified in Figures 1 and 2. Immediate release, as the name implies, precludes any significant delay in the release of the selected active ingredient in the dosage form. Hence, the claimed "burst release" dosage forms are not encompassed by or even suggested by an immediate release tablet. For these reasons, Applicants request that the Examiner reconsider and withdraw the obviousness rejection based on WO '745 in view of Chen and further in view of Sangekar.

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Applicants submit that the present application is now in condition for allowance. In the event that minor amendment will further prosecution, Applicants request that the Examiner contact the undersigned representative.

Respectfully submitted,

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